



**U. S. Department of Justice**  
Drug Enforcement Administration  
Office of Training  
P.O. Box 1475  
Quantico, Virginia 22134-1475

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SEP 25 2003

Mr. Steve Mays  
Manager, Regulatory Affairs  
Amerisource Bergen  
P.O. Box 959  
Valley Forge, Pennsylvania 19482

Dear Mr. Mays:

This letter is to confirm previous arrangements made by the Drug Enforcement Administration (DEA) Office of Training Class Coordinator Dorothy Coursey for a tour of the Bergen Brunswig facility in Richmond, Virginia, by our Diversion Investigator Trainees. I appreciate your cooperation, and I am certain that the visit to your distribution plant will be a valuable learning experience for our students.

The visit to Bergen Brunswig is scheduled for Friday, October 31, 2003. Approximately 30 employees, participating in the tour, will be arriving by bus at approximately 2 p.m. and we will depart your facility at approximately 4 p.m. for the return trip to Quantico, Virginia.

Again, thank you for your cooperation and support of the DEA Office of Training. Ms. Coursey will be in contact with you regarding further arrangements. In the meantime, if you should have any questions, please do not hesitate to contact her at (703) 632-5180.

Sincerely,

A handwritten signature in black ink, appearing to read "William J. McCarty".

John R. McCarty  
Special Agent in Charge

AM-WV-00782

# **Controlled Substance Regulatory Compliance**

**Presented by AmerisourceBergen  
Corporation in cooperation with the Drug  
Enforcement Administration**

Steve Mays

Director, Regulatory Affairs

Security and Regulatory Affairs Dept.

AmerisourceBergen Corporation (ABC)

Valley Forge, PA

## **Statement of Goals**

- The goal of this program is to provide the participants with an overview of the Pharmaceutical (Drug) Wholesale industry and the Wholesaler's compliance with 21 C.F.R. 1300 to the End. In addition, we will provide examples and methods of standard operating procedures of a full-line pharmaceutical wholesaler in an attempt to educate and thus enhance and build on the good working relationship between the Industry and DEA.

# Objectives

- At the end of the presentation attendees should:
  - Understand the basic functions of a drug wholesaler with regard to distribution of controlled substances
  - Be familiar with the basic structure and departments of a drug wholesaler
  - Understand the Industry, basic operations and procedures and how they relate to 21 CFR 1300 to the end
  - Evaluate and understand the different types of reports and documents available during an audit

# Wholesale Drug Distributors

- There are over 3,000 different manufacturers of pharmaceuticals and health care products in the United States
  - ABC maintains approximately 140,000 SKUs (stock keeping units)
- There are over 130,000 pharmacy sites
  - Retail
  - Closed Door
  - Hospital

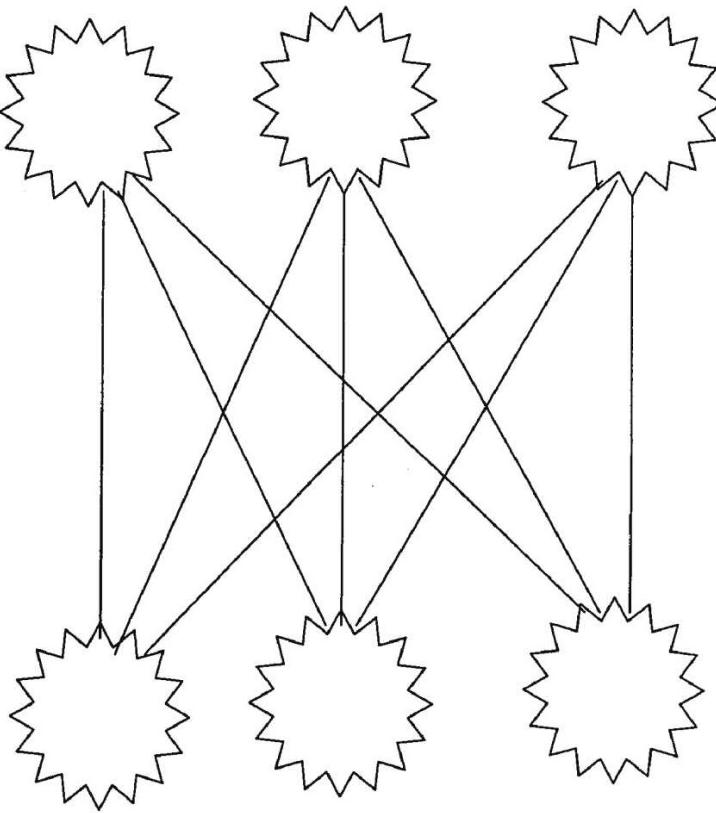
## ROLE OF THE WHOLESALE DISTRIBUTOR

### Without Distributors

Manufacturers      Pharmacies

Confusion and Complexity

If all 130,000 pharmacy sites ordered product from all 3,000 manufacturers once a month the industry would generate 4.9 billion transactions each year



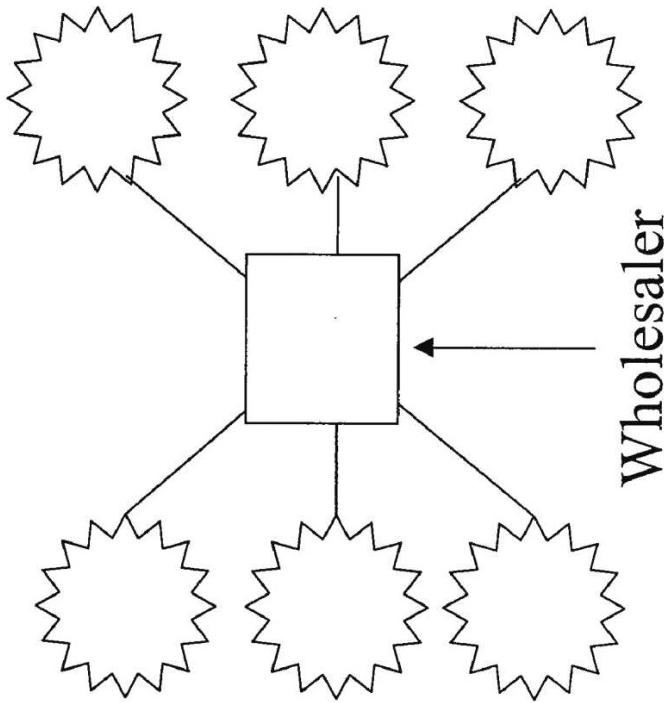
## ROLE OF THE WHOLESALE DISTRIBUTOR

### With Distributors

Control and Common  
Sense

Manufacturers

Pharmacies



Utilizing the 80 drug  
wholesalers that  
number is cut to 124  
million transactions  
(97% reduction in  
transactions)

# Wholesale Drug Distributors

- There are approximately 80 wholesalers who operate approximately 230 distribution centers nationwide which generate approximately \$120 billion in sales annually
- The top 3 wholesalers account for approximately 90% of the market
- In the past decade the industry has cut operating expenses by over 30 percent
- Cutting operating expenses has not curbed the steady decline in profit margins
- Average product mark-up is 1%
- Estimated net profits for Wholesale Drug Distributor is less than 1 percent (0.65%) of sales

## **Cost of Goods**

- ABC's cost on Prozac (\$4,400)
  - At 1% mark-up, a distribution facility would need to sell \$440,000 dollars of product to recoup the loss of one bottle
- ABC's cost on a case of Claritin (\$34,000)
  - At 1% mark-up, a distribution facility would need to sell \$3.4 million of product to recoup the loss of one case

# AmerisourceBergen Corporation

- AmerisourceBergen is the largest pharmaceutical services company in the United States dedicated solely to the pharmaceutical supply chain. It is the leading distributor of pharmaceutical products and services and is also a leader in the long term care pharmacy and workers' compensation fulfillment marketplaces.
- ABC has been in business since 1889
- ABC 2003 revenue - \$45 billion
- Employs 14,000 people
- ABC is ranked #24 on the Fortune 500 list
- Operates 170 separate DEA registered locations
- ABC subsidiaries (ABSG, Pharmerica, AHP)

# AmerisourceBergen Drug Company

## ► Operational Time Line (six days/week)

- Receiving (6:00am - 2:00pm)- approx. \$125-190 million daily
- Ordering (6:00am - 9:00pm) - approx. 100 - 1,000 night
- Picking (12:00pm - 3:00 am) - approx. 10K - 70K Lines
- Shipping (10:00pm - 6:00am)
- Delivery (7:00 am - 4:00pm) - local and line haul

# AmerisourceBergen Drug Company

- Drug Enforcement Administration Audits
  - Average approximately 12 audits each year
  - Each distribution center audited once every 3-5 years
- ABC Security and Regulatory Compliance Audits
  - Average approximately 30 audits each year
  - Each distribution center audited once every 6 - 18 months
- Other Regulatory Agencies Impacting Distribution
  - FDA (PDM&A & New Food Handler Registration)
  - State Boards of Pharmacy/Departments of Health
  - Dept. of Transportation/FAA
  - OSHA
  - EPA (Rx Waste)
  - HIPAA (Patient Privacy)
  - Bureau of Wholesale Furniture

# **Code of Federal Regulations**

- Interpretation
  - Between different facets of the Industry (Phcy, Dist, Mfg's)
  - Between Industry and DEA
  - Between DEA Field Offices and/or Washington

# **21 CFR 1301 - Security**

- 1301.71 - provide effective controls to guard against theft and diversion (Internal/External)
  - Building Security
    - Physical Controls
      - Perception/Reality
      - Security Systems (alarm, access control, CCTV, etc.)
      - Segregated Areas (lobby, office, warehouse, parking)
    - Policy and Procedures
      - Employee entrance
      - Emergency exits
      - Visitor log and badges
      - No packages (purses, backpacks, etc.) in warehouse
      - No picking aprons outside warehouse

# 21 CFR 1301 - Security

- 1301.72 - Controlled Drug physical security
  - Vault & Cage
  - Physical
    - construction (concrete, modular, wire gauge)
    - security systems (different detection sensors)
  - Policy and Procedures
    - Access lists
    - Shipping and Receiving policies (DBL check, log)
    - Inventory control
    - Accountability is key

## **21 CFR 1301 - Security**

- 1301.74 - Other security controls
  - Good faith license inquiry
  - MOST IMPORTANT FUNCTION
  - Wholesale distributors have an express duty to verify licensure and registration status of its customers
  - Customer File Set Up
    - on-site customer inspection
    - retain copy of each customer's registration
    - DEA information entered into computer system exactly as represented on actual registration certificate
    - only delivery to address in system

# **21 CFR 1301 - Security**

- Customer File Maintenance
  - Customer DEA Review Report (NTIS)
    - reviewed monthly by each distribution center
    - also reviewed by corporate
  - Federal Register review daily
  - 30 and 60 day expiration reports printed at distribution centers
- License expiration notifications printed on invoices
- Computer system automatically "blocks" orders of expired registrations

## **21 CFR 1301 - Security**

- 1301.74 - Other security controls
  - Suspicious order reporting system
    - Suspicious orders include orders of unusual size, deviating substantially from a normal pattern, and/or unusual frequency
    - Automated reporting system
    - Flexible reporting timeframes
    - Customer specific (retail, hospital, physician, etc.)

## **21 CFR 1301 - Security**

- 1301.74 - Other security controls
- Theft/loss reporting (DEA Form 106)
- Common and contract carriers
- Narcotic Treatment Center deliveries

# **21 CFR 1301 - Security**

- 1301.90 & .93 - Employee Screening
  - Prospective employees including temporary associates
- All Associates
  - Justifacts - ALL felony & misdemeanor convictions
- "Compliance Critical" Personnel
  - DEA - Drug related charges
  - Annual Justifacts

# 21 CFR 1304 - Records & Reports

- 1304.04 - Maintenance of records and inventories
  - 3 years plus current
  - Central Recordkeeping
    - not including executed DEA Form 222's or inventories
  - Records must be available within two business days of a written request
  - Schedule II records must be stored separately
  - Schedule III-V records stored separately or in a readily retrievable manner

# 21 CFR 1304 - Records & Reports

- 1304.11 - Inventory requirements
  - Complete and accurate record of all controlled substances on hand on the date the inventory is taken
  - ABC Policy and Procedures regarding shipping, receiving and returns
  - Inventories
    - Daily transaction activity counts (detect errors)
    - End of Month inventory of all Controlled Substances (saleable & unsaleable)
    - Year End ARCos - Schedule II & III narcotics
    - Biennial - a complete inventory at least every two years

# **21 CFR 1304 - Records & Reports**

- Area of confusion during audits/inspections
- 1304.22 - Records for distributors
  - Product name, description, quantity, name, addresses, DEA registration number, for all transactions (sales, receipt, credit, debit, etc.)
  - All of this information is available
- 1304.33 Reports to ARCOS
  - Filed monthly
  - All Schedule II and Schedule III narcotic products



 AmerisourceBergen  
AMERISOURCEBERGER-PADUCAH  
322 NORTH 3RD STREET  
PADUCAH, KY 42001  
DEA# PLE032627 PH# 800-945-2472

## REPORT NUMBER: RPT-01

BOTTLES

## CREDIT MEMO

ROUTE/STOP 383-10

3 BAPTIST HEALTHCARE SYST, INC-CITY  
CENTRAL BAPTIST HOSP DEPT PHCY  
1740 NICHOLASVILLE ROAD  
LEXINGTON, KY 40503  
4815  
27760543

SAC

BAPTIST HEALTHCARE SYST, INC-CITY

CENTRAL BAPTIST HOSP DEPT PHCY  
1740 NICHOLASVILLE ROAD  
LEXINGTON, KY 40503  
4815  
27760543

Product Code	Item Description	Quantity	Reference Number	Line Total	Unit Price	Line Total	Unit Price
4454704	2 BUTORPHANOL 20MG/ML IN#3017166 P014 4815	10ML	4010	55390018510	4110	8220	2001

## **21 CFR 1305 - Order Forms**

- 1305.03, .06, .09 & .11 - An order form (DEA Form 222) is required for each distribution of a Schedule II controlled substance
  - Alterations, incomplete
- 1305.07 - Power of Attorney
  - Authorized associates to sign DEA Form 222's
- Each DEA Form 222 is double-checked and matched against work order for accuracy and completeness
- 1305.15 - Cancellations
  - Purchaser cancellations
  - Supplier cancellations
- Automation will positively impact the Industry

# **21 CFR 1309 – Listed Chemicals**

- Registration, Recordkeeping and Reporting
- 1309.21 - (Registration) Every person who distributes List I Chemicals shall obtain annually a registration specific to List I Chemicals
- Exemptions
  - DEA Controlled Substance registration
  - "retail distributor"
- 1309.23 - Separate registration for separate locations
  - System automatically blocks customers without license

# 21 CFR 1310 – Listed Chemicals

- 1310.03 - (Recordkeeping) Required Records
  - Regulated transactions
- 1310.04 - Maintenance of Records
  - Regular business records are acceptable
  - Current plus 2 years
  - Central location record retention acceptable
  - "Readily Retrievable"

# 21 CFR 1310 – Listed Chemicals

- 1310.05 - (Reporting) Required Reports
  - Extraordinary quantity
  - Uncommon method of payment or delivery
  - Excessive loss or disappearance
- Reporting requirements for Chemicals are different than Controlled Substances
  - Oral notification upon discovery of loss
  - Written report must be filed within 15 days of oral notification
  - No DEA Form 106

# Future Impact

- Crime
  - Theft/Burglary
  - Counterfeit Product
- Controlled Substance Ordering System (CSOS)
- Listed Chemicals Storage Requirements
- Rescheduling of certain products

# Questions ?

- Industry
- AmerisourceBergen Corporation
- Registration
- Security
- Records and Reports
- Order Forms
- Listed Chemicals